Message

From: McNally, Robert [Mcnally.Robert@epa.gov]
Sent: 3/12/2020 9:19:22 PM
To: Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Overstreet, Anne [overstreet.anne@epa.gov]
CC: Bohnenblust, Eric [Bohnenblust.Eric@epa.gov]
Subject: RE: Rule Comment response follow up

Left VM

From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Thursday, March 12, 2020 5:04 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Overstreet, Anne <overstreet.anne@epa.gov>
Cc: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Subject: Rule Comment response follow up

Bob and Anne,

Please see a follow up to Rick's note below. Eric's description is consistent with my conversation with him earlier today. We are suggesting a slight tweak re: response to the notification process and providing the comments we intend to send back through. My understanding is that we will send comments back through, OMB is setting up a communication meeting with USDA, and we would like senior leadership to engage on the issues below. Thanks.

Mike

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Thursday, March 12, 2020 2:08 PM
To: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Comment response timeframes and issues for management for genome editing rule/effects on Oxitec EUP

Mike,

Given the response from Alex, we are working to figure out how and when to set up a meeting with USDA to coordinate messaging for the two rules. In addition, we would like to elevate the two issues below for resolution:

Notification: For responding to the notification comments, we will plan to proceed slightly differently than we had indicated and in our response will indicate "the Administrator has directed EPA to have the notification process, and that EPA is also requesting comment on the proposed mandatory notification process" instead of asking for comment on the merits of a voluntary approach. Note we think this will hopefully provide more beneficial public responses on how the mandatory notification process may be best utilized and more in line with the Administrator's direction to include a notification. We believe this notification issue needs to be elevated, because USDA is insistent there be no notification process or a voluntary notification process throughout the three rounds of interagency review and NEC has stated their preference is for no notification as well. USDA's latest comment is provided in blue, NEC's latest comment is in grey below:

USDA:

1) This reviewer remains concerned that the EPA's insistence on a mandatory notification and confirmation process ignores the mandate of President's Executive Order (EO) on agricultural biotechnology to "avoid undue regulatory burdens". Under EPA's current exemption for PIPs from sexually compatible plant created through conventional breeding (40 CFR 174.25), there is no required notification to and confirmation from EPA. Therefore, it appears that these requirements for PIPs from sexually compatible plants developed through biotechnology hinges on the process rather than any risk they may present. This would be counter to the EO's stated policy to "avoid arbitrary or unjustifiable distinctions across like products developed through different technologies".

We appreciate EPA's concern that PIPs could be created that may express a toxic substance at levels or locations that may cause risk to human health or the environment. We question whether PIPs from sexually compatible plants created though biotechnology present novel and/or additional concern than those created through conventional breeding, and therefore need additional regulatory scrutiny.

We suggest that EPA develop a voluntary process consistent to what is currently employed by APHIS and expanded upon in the pending revision to 7 CFR 340. The EPA proposal prevents an exemption "until EPA notifies the submitter in writing that the plant incorporated protectant meets the criteria for exemption" and at any time "may require additional information to assess whether a plant-incorporated protectant meets the criteria for exemption" leaving submitters at the whims of EPA reviewers. This perpetuates regulatory uncertainty and imposes a regulatory burden on all developers (which could be particularly burdensome on smaller developers), could stifle innovation.

NEC: Since USDA is going with a voluntary notification procedure, why wouldn't EPA consider such an approach or at least take comment on it? Cant EPA, as USDA is doing, simply provide an exemption from review based on the presumed safety of things found in nature?

FDA feed/Animal health issue: Moreover, we also believe the issue FDA continues to raise about animal health in the FFDCA tolerance exemption section need to be elevated because FDA has raised this issue three times now and we do not foresee immediate resolution which could lead to considerable delays and a much longer OMB review. EPA's draft response is below which is provided in more detail than in the previous email. We are happy to provide more information if needed for further discussion.

Line 332 - EPA: *At several points throughout the proposed rule FDA raised concerns specific to animal health. These included species-specific differences regarding toxicity, animal consumption of plant tissue not commonly consumed by humans, and differences in processing of food for human consumption and food and feed for animal consumption. In response to similar comments, EPA previously provided an overview of the scope of the risk assessment the Agency conducts for pesticides (including PIPs) under FFDCA and FIFRA and would like to refer FDA to these earlier discussions. EPA would like to especially highlight the response in the second comment bubble in this proposed rule (in red) and the response to comment #1 in the comment document that was provided separately by OMB. Any aspects discussed by FDA that are outside of the scope of the standard risk assessment raises larger programmatic questions for EPA. These specific concerns regarding animal safety may therefore be more appropriately discussed in a separate forum between the two Agencies.*

Eric Bohnenblust, Ph.D
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Emerging Technologies Branch (ETB)
Biopesticides and Pollution Prevention Division (BPPD)
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From: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Sent: Wednesday, March 11, 2020 4:42 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Subject: FW: Comment response timeframes and issues for management for genome editing rule/effects on Oxitec EUP

From: McNally, Robert <Mcnally.Robert@epa.gov>
Sent: Wednesday, March 11, 2020 4:04 PM
To: Keigwin, Richard <Keigwin.Richard@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Comment response timeframes and issues for management for genome editing rule/effects on Oxitec EUP

Sounds good

From: Keigwin, Richard <Keigwin.Richard@epa.gov>
Sent: Wednesday, March 11, 2020 11:49 AM
To: McNally, Robert <Mcnally.Robert@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: Re: Comment response timeframes and issues for management for genome editing rule/effects on Oxitec EUP

I spoke with Alex regarding issues 1 and 2.

Ex. 5 Deliberative Process (DP)

Rick Keigwin
Director, Office of Pesticide Programs
U.S. Environmental Protection Agency
Phone: 703-305-7090
Website: http://www.epa.gov/pesticides
Sent from my iPhone (Please excuse typos!)

> On Mar 10, 2020, at 4:16 PM, McNally, Robert <Mcnally.Robert@epa.gov> wrote:
>
> Rick,

Ex. 5 Deliberative Process (DP)

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Let us know if you have questions.

Thanks

Bob